MLN Matters Number: MM4350 Related Change Request (CR) #: 4350

Related CR Release Date: March 31, 2006 Effective Date: March 20, 2006

Related CR Transmittal #: R50NCD and R898CP Implementation Date: April 3, 2006

External Counterpulsation (ECP) Therapy

Provider Types Affected

Providers, physicians, and suppliers who bill Medicare contractors (fiscal intermediaries (FIs) and carriers) for external counterpulsation (ECP) therapy services

Key Points

- The Centers for Medicare & Medicaid Services (CMS) initiated a reconsideration of the National Coverage Determination (NCD) for ECP therapy in response to a request to reconsider that policy and expand coverage to certain additional cardiac conditions.
- Effective March 20, 2006, CMS decided to continue current coverage for ECP therapy, and not to expand coverage to additional cardiac indications.
- The CMS determined that the evidence is **not** adequate to conclude that ECP therapy is reasonable and necessary for (1) Canadian Cardiovascular Society Classification (CCSC) II angina, (2) heart failure (New York Heart Association (NYHA) Class II/III stable heart failure symptoms with an ejection fraction of ≤ 35%, NYHA Class II/III stable heart failure symptoms with an ejection fraction of ≤ 40%, NYHA Class IV heart failure, and acute heart failure), (3) cardiogenic shock, or (4) acute myocardial infarction.
- Continuing with current policy, effective for services performed on or after July 1, 1999, ECP therapy is considered reasonable and necessary relative to cardiac conditions only when the conditions for coverage identified in Publication 100-3, Section 20.20 of the *Medicare National Coverage Determinations Manual* (NCD Manual) are met.
- All other cardiac conditions that are not otherwise specified as nationally covered for the use of ECP remain nationally non-covered.

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Background

Prior to July 1999, ECP therapy was non-covered for all indications. The coverage policy was amended, effective July 1, 1999, to allow coverage for ECP therapy under certain circumstances. Coverage for ECP was provided only for patients who were diagnosed with disabling angina (Class III or Class IV, CCSC or equivalent classification) and who, in the opinion of a cardiologist or cardiothoracic surgeon, are not readily amenable to surgical intervention.

Under this policy decision, the therapy was identified as Enhanced External Counterpulsation. Subsequent reconsiderations of the NCD in February 2000 and October 2001:

- Changed the description of the service back to ECP;
- Removed the requirement limiting coverage to specific ECP systems; and
- Clarified that the policy only pertains to ECP devices intended for the treatment of cardiac conditions.

Additional Information

Publication 100-04, *The Medicare Claims Processing Manual*, Chapter 32, Section 130, is updated to manualize current billing and payment requirements for both FIs and carriers. The revised section is attached to CR4350, which is the official instruction issued to your FI or carrier regarding changes mentioned in this article, MM4350. There are two transmittals related to CR4350. The first is the transmittal conveying the NCD, which is available at

http://www.cms.hhs.gov/Transmittals/downloads/R50NCD.pdf, and the second, which revises the *Medicare Claims Processing Manual*, is at http://www.cms.hhs.gov/Transmittals/downloads/R898CP.pdf on the CMS web site.

Please refer to your local FI or carrier if you have questions about this issue. To find their toll-free phone number, go to http://www.cms.hhs.gov/apps/contacts/ on the CMS web site.

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